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201-16176B

I U C L I D

Data Set

Existing Chemical : ID: 13752-51-7
CAS No. : 13752-51-7
CAS Name : N-oxydiethylenethiocarbamyl-N-oxydiethylenesulfenamide
EC No. : 237-335-9

Producer related part
Company : American Chemistry Council Rubber and Plastic Additives Panel
Creation date : 21.06.2005

Substance related part
Company : American Chemistry Council Rubber and Plastic Additives Panel
Creation date : 21.06.2005

Status :
Memo :

Printing date : 08.09.2005
Revision date :
Date of last update : 08.09.2005

Number of pages : 53

Chapter (profile) : Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile) : Reliability: without reliability, 1, 2, 3, 4
Flags (profile) : Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE),
Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1. General Information

Id 13752-51-7

Date 08.09.2005

Telefax :
Telex :
Cedex :
Email :
Homepage :

21.06.2005

Type : cooperating company
Name : Crompton Corporation
Contact person :
Date :
Street :
Town :
Country : United States
Phone :
Telefax :
Telex :
Cedex :
Email :
Homepage :

21.06.2005

Type : cooperating company
Name : Eliokem, Inc
Contact person :
Date :
Street :
Town :
Country : United States
Phone :
Telefax :
Telex :
Cedex :
Email :
Homepage :

21.06.2005

Type : cooperating company
Name : Flexsys America L.P.
Contact person :
Date :
Street :
Town :
Country : United States
Phone :
Telefax :
Telex :
Cedex :
Email :
Homepage :

21.06.2005

Type : cooperating company
Name : Goodyear Tire & Rubber Company
Contact person :
Date :
Street :
Town :

1. General Information

Id 13752-51-7

Date 08.09.2005

Country : United States
Phone :
Telefax :
Telex :
Cedex :
Email :
Homepage :

21.06.2005

Type : cooperating company
Name : Noveon, Inc (formerly BF Goodrich)
Contact person :
Date :
Street :
Town :
Country : United States
Phone :
Telefax :
Telex :
Cedex :
Email :
Homepage :

21.06.2005

Type : cooperating company
Name : R.T. Vanderbilt Company Inc.
Contact person :
Date :
Street :
Town :
Country : United States
Phone :
Telefax :
Telex :
Cedex :
Email :
Homepage :

21.06.2005

Type : cooperating company
Name : The Lubrizol Corporation
Contact person :
Date :
Street :
Town :
Country : United States
Phone :
Telefax :
Telex :
Cedex :
Email :
Homepage :

21.06.2005

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type :
Substance type : organic
Physical status : solid
Purity : 95 - 99 % w/w
Colour :
Odour :

Source : American Chemistry Council Rubber and Plastic Additives Panel
25.04.2001

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

Morpholine, 4-[(morpholinethiocarbonyl)thio]-

Source : American Chemistry Council Rubber and Plastic Additives Panel
25.04.2001

Cure-Rite® 18

Source : American Chemistry Council Rubber and Plastic Additives Panel
21.06.2005

Good-Rite® 3030x18

Source : American Chemistry Council Rubber and Plastic Additives Panel
21.06.2005

1.3 IMPURITIES

Purity :
CAS-No : 729-46-4
EC-No :
EINECS-Name : Dimorpholine Thiuram Disulfide
Molecular formula :
Value : < 5 % w/w

Source : American Chemistry Council Rubber and Plastic Additives Panel
25.04.2001

Purity :
CAS-No : 34986-62-4

1. General Information

Id 13752-51-7

Date 08.09.2005

EC-No :
EINECS-Name : [4-(4'-morpholinodithion) thioxomethyl-morpholine]
Molecular formula :
Value : < .5 % w/w

Source : American Chemistry Council Rubber and Plastic Additives Panel
25.04.2001

Purity :
CAS-No : 110-91-8
EC-No : 203-815-1
EINECS-Name : morpholine
Molecular formula :
Value : < .02 % w/w

Source : American Chemistry Council Rubber and Plastic Additives Panel
25.04.2001

Purity :
CAS-No : 59-89-2
EC-No :
EINECS-Name : N-nitrosomorpholine
Molecular formula :
Value : < .005 % w/w

Source : American Chemistry Council Rubber and Plastic Additives Panel
25.04.2001

1.4 ADDITIVES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.6.3 PACKAGING

1.7 USE PATTERN

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

1. General Information

Id 13752-51-7

Date 08.09.2005

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2.1 MELTING POINT

Value	:	124.3 °C	
Sublimation	:		
Method	:	other: (calculated) MPBPWIN (v1.31)	
Year	:	1999	
GLP	:	no	
Test substance	:	other TS: molecular structure	
Remark	:	Comparable to BFG MSDS data of ≥ 132 C	
Result	:	Melting Point: 251.84 deg C (Adapted Joback Method)	
	:	Melting Point: 92.44 deg C (Gold and Ogle Method)	
	:	Mean Melt Pt : 172.14 deg C (Joback; Gold,Ogle Methods)	
	:	Selected MP: 124.32 deg C (Weighted Value)	
Source	:	American Chemistry Council Rubber and Plastic Additives Panel	
Reliability	:	(2) valid with restrictions	
Flag	:	Critical study for SIDS endpoint	
25.04.2001			(14)
Value	:	130 - 140 °C	
Sublimation	:		
Method	:	other: Capillary melt point tube and Thomas Hoover Melt Point Apparatus	
Year	:	2003	
GLP	:	no	
Test substance	:	other TS: Commercial Cure-Rite® 18	
Remark	:	The specification for Commercial Cure-Rite® 18 is 130.0 -140.0 degree C. The test is conducted using a capillary melt point tube and Thomas Hoover Melt Point Apparatus. The test material is ground and packed 3 mm to 6 mm high in the capillary tube. Bath temperature is started 10-15° C below expected melt point. Temperature automatically increases at a rate of 1.5° C/minute. The initial melt point is the temperature where liquid forms a meniscus. The final melt point is the temperature where no further melting is observed.	
Result	:	130.0 -140.0 degree C	
Reliability	:	(2) valid with restrictions	
Flag	:	Critical study for SIDS endpoint	
21.06.2005			(13)

2.2 BOILING POINT

Value	:	130 - 140 °C at	
Decomposition	:		
Method	:	other:Capillary melt point tube and Thomas Hoover Melt Point Apparatus	
Year	:	2003	
GLP	:	no	
Test substance	:	other TS:Commercial Cure-Rite® 18	
Remark	:	Commercial Cure-Rite® 18 decomposes before it can boil. Decomposition starts at the melting point.	
Reliability	:	(2) valid with restrictions	
Flag	:	Critical study for SIDS endpoint	
21.06.2005			(13)
Value	:	353 °C at	
Decomposition	:		
Method	:	other: (calculated) MPBPWIN (v1.31) - Adapted Stein and Brown Method	

2. Physico-Chemical Data

Id 13752-51-7

Date 08.09.2005

Year : 1999
GLP : no
Test substance : other TS: molecular structure

Remark : BFGoodrich MSDS indicates Not Applicable
Source : American Chemistry Council Rubber and Plastic Additives Panel
Flag : Critical study for SIDS endpoint
21.06.2005 (14)

2.3 DENSITY

Type : density
Value : .6 g/cm³ at °C
Method : other: historical data
Year :
GLP :
Test substance : as prescribed by 1.1 - 1.4

Source : American Chemistry Council Rubber and Plastic Additives Panel
25.04.2001 (1)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value : .00001153 hPa at 25 °C
Decomposition :
Method : other (calculated): MPBPWIN (v1.31)
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Result : Vapor Pressure Estimations (25 deg C):
(Using BP: 352.97 deg C (estimated)) (Using MP: 124.32 deg C (estimated))
VP: 5.17E-006 mm Hg (Antoine Method)
VP: 1.15E-005 mm Hg (Modified Grain Method)
VP: 2.32E-005 mm Hg (Mackay Method)
Selected VP: 1.15E-005 mm Hg (Modified Grain Method)

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
22.06.2005 (14)

2.5 PARTITION COEFFICIENT

Partition coefficient :
Log pow : -.84 at °C
pH value :
Method : other (calculated): KOWWIN Program (v1.65)
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Source : American Chemistry Council Rubber and Plastic Additives Panel

2. Physico-Chemical Data

Id 13752-51-7

Date 08.09.2005

Reliability	:	(2) valid with restrictions	
	:	Accepted calculation method	
Flag	:	Critical study for SIDS endpoint	
25.04.2001			(14)
Partition coefficient	:	octanol-water	
Log pow	:	1.65 at °C	
pH value	:	7.1	
Method	:	OECD Guide-line 117 "Partition Coefficient (n-octanol/water), HPLC Method"	
Year	:	2004	
GLP	:	yes	
Test substance	:	other TS:Cure-Rite® 18, purity: 98.5%	
Remark	:	The study was performed as an approximately neutral pH with the test material in its non-ionised form.	
Reliability	:	(1) valid without restriction	
Flag	:	Critical study for SIDS endpoint	
21.06.2005			(15)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:		
Value	:	62850 mg/l at 25 °C	
pH value	:		
concentration	:	at °C	
Temperature effects	:		
Examine different pol.	:		
pKa	:	at 25 °C	
Description	:		
Stable	:		
Deg. product	:		
Method	:	other: (calculated) WSKOW (v1.36)	
Year	:	1999	
GLP	:	no	
Test substance	:	other TS: molecular structure	
Result	:	Log Kow (estimated) : -0.84 Log Kow (experimental): not available from database Log Kow used by Water solubility estimates: -0.84 Equation Used to Make Water Sol estimate: Log S (mol/L) = 0.796 - 0.854 log Kow - 0.00728 MW + Correction (used when Melting Point NOT available) Correction(s): Value ----- Multi-Nitrogen Type -1.310 Log Water Solubility (in moles/L) : -0.597 Water Solubility at 25 deg C (mg/L): 6.285e+004	
Source	:	American Chemistry Council Rubber and Plastic Additives Panel	
Reliability	:	(2) valid with restrictions	
	:	Accepted calculation method	
Flag	:	Critical study for SIDS endpoint	
25.04.2001			(14)
Solubility in	:	Water	
Value	:	.127 g/l at 20 °C	
pH value	:		
concentration	:	at °C	

2. Physico-Chemical Data

Id 13752-51-7

Date 08.09.2005

Temperature effects :
Examine different pol. :
pKa : at 25 °C
Description :
Stable :
Deg. product :
Method : OECD Guide-line 105
Year : 2004
GLP : yes
Test substance : other TS:Cure-Rite® 18, purity: 98.5%

Remark : In a preliminary test an aliquot (10.0368 g) of ground test material was diluted to 100 ml with glass double-distilled water. After shaking at 30°C for 3 hours and standing at 20°C for 3 hours, the solution was centrifuged at 10000 rpm for 15 minutes, diluted and analyzed.

Based on the preliminary result, mixtures of ground test material and glass double-distilled water were added to three separate flasks.

Sample	Mass of Test Material(g)	Volume of Water(ml)
1	0.1045	100
2	0.1074	100
3	0.1060	100

After addition of glass double-distilled water to the flasks, they were shaken at approximately 30°C and, after standing at 20°C for a period of not less than 24 hours, the contents of the flasks were centrifuged at 10000 rpm for 20 minutes and sampled excluding excess, undissolved test material. The pH of each solution was measured.

Due to evidence of hydrolysis in the definitive test samples, an additional short-term solubility assessment sample was prepared. An aliquot (0.1021 g) of ground test material was diluted to 100 ml with glass double-distilled water. After shaking at 30 °C for 1 hour and standing at 20 °C for 1 hour, the contents of the flask was centrifuged at 10000 rpm for 20 minutes and sampled excluding excess, undissolved test material. The concentration of test material in the sample solutions was determined by high performance liquid chromatography (HPLC).

Duplicate aliquots (A and B) of the sample solution were diluted by a factor of 2 using acetonitrile.

Duplicate standard solutions of test material were prepared in acetonitrile: water (50:50 v/v) at a nominal concentration of 60 mg/l.

The concentration (g/l) of test material in the sample solutions is shown below.

Sample Number/	Time Shaken at~ 30°C (hours)/	Time Equilibrated at 20°C (hours)/Concentration (g/l)/Solution pH
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1- 24/ 24/ 0.104/ 8.6

2- 48/ 24/ 9.45 x 10⁻²/ 8.8

3- 72/ 24/ 8.29 x 10⁻²/ 8.8

Short-term assessment- 1/ 1/ 0.127/ 6.8

Overall result: solubility of 0.127 g/l of solution at 20.0 ± 0.5 °C

It is evident from the information obtained in the hydrolysis study, chromatography generated and data relating to the pH of the test material in water that significant hydrolysis of the sample solution occurred during the course of the water solubility test. Therefore the overall result has been taken from the short-term assessment sample. This value was also in close agreement with the preliminary test result of 0.124 g/l, again obtained using reduced saturation and equilibration periods. However it must be noted that due to the reduced time scale of the test, the solutions may not have reached thermodynamic equilibrium.

The water solubility of the test material has been determined to be 0.127 g/l of solution at $20.0 \pm 0.5^{\circ}\text{C}$. However this degree of solubility, due to hydrolysis of the test material in water, was observed only in a short-term assessment sample using reduced saturation and equilibration periods of 1 hour.

Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
21.06.2005

(15)

2.6.2 SURFACE TENSION**2.7 FLASH POINT****2.8 AUTO FLAMMABILITY**

Value : 275 °C at

Remark : Self-Ignition Temperature
Source : American Chemistry Council Rubber and Plastic Additives Panel
25.04.2001

(1)

2.9 FLAMMABILITY**2.10 EXPLOSIVE PROPERTIES****2.11 OXIDIZING PROPERTIES****2.12 DISSOCIATION CONSTANT****2.13 VISCOSITY****2.14 ADDITIONAL REMARKS**

3.1.1 PHOTODEGRADATION

Type : air
Light source :
Light spectrum : nm
Relative intensity : based on intensity of sunlight
INDIRECT PHOTOLYSIS
Sensitizer : OH
Conc. of sensitizer : 1560000 molecule/cm³
Rate constant : .000000000002156 cm³/(molecule*sec)
Degradation : 50 % after .6 hour(s)
Deg. product :
Method : other (calculated): AOP (v1.89):
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
Accepted calculation method
Flag : Critical study for SIDS endpoint
21.06.2005

(14)

3.1.2 STABILITY IN WATER

Type : abiotic
t1/2 pH4 : 14.2 minute(s) at 25 °C
t1/2 pH7 : 44.4 minute(s) at 25 °C
t1/2 pH9 : at °C
Deg. product :
Method : OECD Guide-line 111 "Hydrolysis as a Function of pH"
Year : 2004
GLP : yes
Test substance : other TS:Cure-Rite® 18, purity: 98.5%

Remark : Sample solutions were prepared in stoppered glass flasks at a nominal concentration of 4.0 x 10⁻² g/l in the three buffer solutions. A 1% co-solvent of acetonitrile was used to aid solubility. The solutions were shielded from light whilst maintained at the test temperature.

In a preliminary test sample solutions at pH 4, 7 and 9 were maintained at 50.0 ± 0.5°C for a period of 2.4 hours, 24 hours and 120 hours respectively. Results from the preliminary test showed it was necessary to undertake further definitive testing at pH 4, pH 7 and pH 9. At pH 4, sample solutions were incubated at 0 °C (in duplicate) and 10 °C for periods of 60 minutes and 40 minutes respectively. At pH 7, sample solutions were incubated at 50 °C, 60 °C (in duplicate) and 70 °C for periods of 6 hours, 4 hours and 2 hours respectively. At pH 9, although preliminary testing confirmed hydrolytic instability, the available data was inconclusive with respect to the estimated rate of hydrolysis. Therefore an additional test was performed, incubating a sample solution at 50 °C for a period of 72.5 hours. This test concluded that under these experimental conditions, the hydrolysis kinetics were not pseudo-first order. Therefore a test was performed directly at 25 °C, incubating a sample solution for a period of 263 hours. Due to hydrolytic instability at pH 4, testing was performed under the physiologically relevant conditions of pH 1.2 at 37 °C. A sample solution was incubated under these test conditions for a period of 15 minutes.

Aliquots of the sample solutions were taken from the flasks at various times and the pH of each solution recorded.

The concentration of the sample solution was determined by high performance liquid chromatography (HPLC). Duplicate aliquots (A and B) of sample solution were diluted by a factor of 2 using acetonitrile for testing at pH 4, pH 7 and pH 9. For testing at pH 1.2 the sample solution was analysed directly without further dilution. Duplicate standard solutions of test material were prepared in acetonitrile: relevant buffer solution (50:50 v/v) at a nominal concentration of 20 mg/l for testing at pH 4, pH 7 and pH 9. For testing at pH 1.2, duplicate standards of test material were prepared in acetonitrile at a nominal concentration of 40 mg/l.

The concentration of sample solutions (g/l) was calculated using the HPLC peak areas of the samples and standard solutions.

Preliminary testing at 50 C indicated that the test material was hydrolytically unstable, defined by the method guideline as less than 90% remaining after 120 hours at 50 C, at all three pH's. The results were complete hydrolysis after 2.4 hours at pH 4, 0.4% remaining after 24 hours at pH 7, and less than 0.1% remaining after 120 hours at pH 9.

The test material concentrations at the given time points are shown below

pH 4 at $0.0 \pm 0.5^\circ\text{C}$, Determination A

Concentration at (Time (Hours)) 0, 0.167, 0.333, 0.500, 0.667, 0.833, 1.000

Concentration (g/l): 3.70×10^{-2} / 3.23×10^{-2} / 2.84×10^{-2} / 2.57×10^{-2} / 2.39×10^{-2} / 2.11×10^{-2} / 1.95×10^{-2}

Log10 [concentration (g/l)]: -1.43/-1.49/-1.55/-1.59/-1.62/-1.68/-1.71

% of initial: 100 / 87.4 / 76.7 / 69.6 / 64.6 / 57.0 / 52.8

pH 4 at $0.0 \pm 0.5^\circ\text{C}$, Determination B

Concentration at (Time (Hours)): 0, 0.167, 0.333, 0.500, 0.667, 0.833, 1.000

Concentration (g/l): 3.83×10^{-2} / 3.21×10^{-2} / 2.98×10^{-2} / 2.51×10^{-2} / 2.33×10^{-2} / 2.05×10^{-2} / 1.85×10^{-2}

Log10 [concentration (g/l)]: -1.42/ -1.49/ -1.53/ -1.60/ -1.63/ -1.69/ -1.73

% of initial: 100/ 83.8/ 77.9/ 65.6/ 61.0/ 53.7/ 48.4

pH 4 at $10.0 \pm 0.5^\circ\text{C}$

Concentration at (Time (Hours)): 0, 0.167, 0.250, 0.333, 0.417, 0.500, 0.667

Concentration (g/l): 3.83×10^{-2} / 3.04×10^{-2} / 2.73×10^{-2} / 2.45×10^{-2} / 2.18×10^{-2} / 1.97×10^{-2} / 1.69×10^{-2}

Log10 [concentration (g/l)]: -1.42/ -1.52/ -1.56/ -1.61/ -1.66/ -1.71/ -1.77

% of initial: 100/ 79.3/ 71.3/ 63.9/ 56.8/ 51.4/ 44.1

pH 7 at $50.0 \pm 0.5^\circ\text{C}$

Concentration at (Time (Hours)): 0, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0

Concentration (g/l): 3.80×10^{-2} / 2.97×10^{-2} / 2.76×10^{-2} / 2.60×10^{-2} / 2.52×10^{-2} / 2.36×10^{-2} / 2.05×10^{-2} / 1.83×10^{-2}

Log10 [concentration (g/l)]: -1.42/ -1.53/ -1.56/ -1.59/ -1.60/ -1.63/ -1.69/ -1.74

% of initial: 100/ 78.1/ 72.7/ 68.4/ 66.3 / 62.1/ 53.9/ 48.1

pH 7 at $60.0 \pm 0.5^\circ\text{C}$, Determination A

Concentration at (Time (Hours)): 0, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0

Concentration (g/l): 3.99×10^{-2} / 3.11×10^{-2} / 2.62×10^{-2} / 2.24×10^{-2} / 1.97×10^{-2} / 1.67×10^{-2} / 1.43×10^{-2} / 1.23×10^{-2}

Log10 [concentration (g/l)]: -1.40/ -1.51/ -1.58/ -1.65/ -1.71/ -1.78/ -1.84/ -1.91

% of initial: 100/ 77.9/ 65.7/ 56.2/ 49.3/ 41.7/ 36.0/ 30.8

pH 7 at $60.0 \pm 0.5^\circ\text{C}$, Determination B

Concentration at (Time (Hours)): 0, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0

Concentration (g/l): 4.03×10^{-2} / 3.08×10^{-2} / 2.67×10^{-2} / 2.30×10^{-2} / 2.01×10^{-2} / 1.74×10^{-2} / 1.49×10^{-2} / 1.28×10^{-2}

Log10 [concentration (g/l)]: -1.40/ -1.51/ -1.57/ -1.64/ -1.70/ -1.76/ -1.83/ -1.89

% of initial: 100/ 76.4/ 66.2/ 57.1/ 49.8/ 43.2/ 37.1/ 31.7

pH 7 at 70.0 ± 0.5 C

Concentration at (Time (Hours)): 0, 0.333, 0.500, 0.667, 1.00, 1.33, 1.67, 2.00

Concentration (g/l): 4.15×10^{-2} / 3.72×10^{-2} / 3.55×10^{-2} / 3.25×10^{-2} / 2.73×10^{-2} / 2.24×10^{-2} / 1.83×10^{-2} / 1.50×10^{-2}

Log10 [concentration (g/l)]: -1.38/ -1.43/ -1.45/ -1.49/ -1.56/ -1.65/ -1.74/ -1.82

% of initial: 100/ 89.6/ 85.6/ 78.4/ 65.7/ 54.1/ 44.1/ 36.1

pH 9 at 50.0 ± 0.5 C

Concentration at (Time (Hours)): 0, 17.5, 21.0, 24.5, 42.5, 45.5, 48.5, 66.5, 72.5

Concentration (g/l): 3.97×10^{-2} / 3.29×10^{-2} / 3.15×10^{-2} / 2.93×10^{-2} / 1.47×10^{-2} / 1.28×10^{-2} / 1.11×10^{-2} / 3.54×10^{-3} / 2.51×10^{-3}

Log10 [concentration (g/l)]: -1.40/ -1.48/ -1.50/ -1.53/ -1.83/ -1.89/ -1.95/ -2.45/ -2.60

% of initial: 100/ 82.8/ 79.3/ 73.7/ 37.0/ 32.3/ 28.0/ 8.91/ 6.33

pH 9 at $25.0 \pm 0.5^\circ\text{C}$

Concentration at (Time (Hours)): 0, 24, 48, 120, 168, 192, 216, 263

Concentration (g/l): 3.91×10^{-2} / 3.85×10^{-2} / 3.89×10^{-2} / 3.19×10^{-2} / 2.12×10^{-2} / 1.61×10^{-2} / 1.05×10^{-2} / 3.84×10^{-3}

Log10 [concentration (g/l)]: -1.41 / -1.42/ -1.41/ -1.50/ -1.67 / -1.79 / -1.98/ -2.42

% of initial: 100/ 98.6/ 99.7/ 81.6/ 54.4/ 41.2/ 26.9/ 9.83

pH 1.2 at $37.0 \pm 0.5^\circ\text{C}$

Concentration at (Time (Hours)): 0, 0.25,

Concentration (g/l): 1.78×10^{-5} / ND

% of initial: -/ -

The kinetics of the study at pH 4 and pH 7 have been determined to be consistent with that of a pseudo-first order reaction as the graphs of log10 concentration versus time are straight lines. At pH 9 the rate of hydrolysis did not indicate pseudo-first order kinetics, with a degree of self-catalysis evident. At 25 C, where an initial plateau was observed prior to any significant, detectable hydrolysis, a third order plot gave the best correlation for the data. It has been observed that the rate of hydrolysis increases with a decrease in pH. The rate constant and estimated half-life at 25°C of the test material are shown below.

pH	Rate constant (s-1)	Estimated half-life at 25°C
4	8.14×10^{-4}	14.2 minutes
7	4.34×10^{-6}	44.4 hours

At pH 9, the test material did not display pseudo-first order kinetics. As such hydrolysis was beyond the scope of the method guideline, testing was performed directly at 25 C. The results, obtained using a third order correlation, are shown below.

Percentage remaining at 25 C	Time (hours)
90%	97.2
75%	132
50%	176
25%	221

10%

262

Reliability
21.06.2005

An additional test was performed under the physiologically relevant conditions of pH 1.2 at 37 C. Under these conditions the test material underwent spontaneous hydrolysis.
: (1) valid without restriction

3.1.3 STABILITY IN SOIL**3.2.1 MONITORING DATA****3.2.2 FIELD STUDIES****3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS**

Type : fugacity model level III
Media : other: air, water, soil, sediment
Air : % (Fugacity Model Level I)
Water : % (Fugacity Model Level I)
Soil : % (Fugacity Model Level I)
Biota : % (Fugacity Model Level II/III)
Soil : % (Fugacity Model Level II/III)
Method : other: EPIWIN v3.12 level III Fugacity Model
Year : 2005

Result : 1000 kg/h emission to these compartments separately
 Air/Water/Soil/Simultaneous 1000 kg/h emission to air, water and soil compartments
 In air 6.44/ 1.6E-05/ 0.00152/ 0.394
 In water 6.58/ 99.9/ 2/ 32.2
 In soil 87/ 0.00022/ 98/ 67.4/
 In sediment 0.00966/ 0.147/ 0.00293/ 0.0472

Test condition : Inputs:
 Molecular weight: 248.36
 Henry's LC: 2.04E-08 atm-m³/mole (user entered)
 Water solubility: 127 mg/L (user entered)
 Vapour pressure: 7.95E-06 mmHg (Mppbpwin program)
 Melting point: 139 deg C (user entered)
 Log Kow: 1.65 (user entered)
 Soil Koc: 18.3 (calc by model)
 Temperature: 25°C
 T1/2 (air): 0.6 hours (estimated using AOPWIN v1.91)
 T1/2 (water): 44.4 hours (user input from abiotic degradation test, pH 7)
 T1/2 (soil): 88.8 hours (estimated using Biowin half-life factor)
 T1/2 (sediment): 399.6 hours (estimated using Biowin half-life factor)

Reliability : (2) valid with restrictions
 Accepted calculation method

Flag : Critical study for SIDS endpoint
 08.09.2005

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3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	: aerobic
Inoculum	: activated sludge, non-adapted
Concentration	: 10 mg/l related to DOC (Dissolved Organic Carbon) related to
Contact time	:
Degradation	: 42 (±) % after 28 day(s)
Result	: other: Not readily biodegradable
Deg. product	:
Method	: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO ₂ evolution)"
Year	: 2004
GLP	: yes
Test substance	: other TS: Cure-Rite® 18, purity: 98.5%
Remark	<p>: The test material was evaluated to determine biodegradability in an aerobic aqueous medium using OECD Guideline No 301B (1992), "Ready Biodegradability; CO₂ Evolution Test", Commission Directive 92/69/EEC (Annex V of Council Directive 67/548/EEC), and US EPA Guidelines OPPTS 835.3110. The degradation of the test material was assessed by the determination of carbon dioxide produced. The test material, at a concentration of 10 mg C/l, was exposed to activated sewage sludge micro-organisms with culture medium in sealed culture vessels in the dark at 21 C for 28 days. Control solutions with inoculum and the standard material, sodium benzoate, together with a toxicity control were used for validation purposes. Samples (2 ml) were taken from the first CO₂ absorber vessel on Days 0, 1, 2, 3, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 27, 28 and 29. The second absorber vessel was sampled on Days 0 and 29. The samples taken on Days 0, 1, 2, 3, 6, 8, 10, 14, 16, 20, 22, 24, 27, 28 and 29 were analyzed for CO₂ immediately. The samples taken on Days 12 and 18 were stored at approximately 20 C. However, these samples were not analyzed for CO₂ as the results obtained from previous and subsequent analyses showed that the level of degradation of the test material did not significantly increase during this time and therefore additional analyses were considered to be unnecessary.</p> <p>The test material attained 42% degradation after 28 days and therefore cannot be considered to be readily biodegradable under the strict terms and conditions of OECD Guideline No 301B. All validation criteria were met for the method (i.e., = 60% degradation by standard control by 14 days, = 25% degradation by toxicity control by 14 days, < 20% difference of the extremes of the replicate values, = 40 mg/l total CO₂ in control at end of test, initial IC content of test material suspension <5% of the TC).</p>
Reliability	: (1) valid without restriction
21.06.2005	

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3.6 BOD₅, COD OR BOD₅/COD RATIO

3. Environmental Fate and Pathways

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3.7 BIOACCUMULATION

Species : other:calculation
Exposure period : at °C
Concentration :
BCF : 3.16
Elimination :
Method : other:BCF Program (v2.13)
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Result : Log Kow (estimated) : -0.84
Log Kow (experimental): not available from database
Log Kow used by BCF estimates: -0.84

Equation Used to Make BCF estimate:

Log BCF = 0.50

Correction(s): Correction Factors Not Used for Log Kow < 1

Estimated Log BCF = 0.500 (BCF = 3.162)

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3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type : other: calculation
Species : other: Fish
Exposure period : 14 day(s)
Unit : mg/l
LC50 : 99248
Limit test :
Analytical monitoring : no
Method : other: ECOSAR v0.99e
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Remark : Chemical may not be soluble enough to measure this predicted effect.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
 25.04.2001

(14)

Type : other: calculation
Species : other: Fish
Exposure period : 96 hour(s)
Unit : mg/l
LC50 : 86036
Limit test :
Analytical monitoring : no
Method : other: ECOSAR v0.99e
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Remark : Chemical may not be soluble enough to measure this predicted effect.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
 25.04.2001

(14)

Type : other: calculation
Species : other: Saltwater Fish
Exposure period : 96 hour(s)
Unit : mg/l
LC50 : 4992 calculated
Limit test :
Analytical monitoring : no
Method : other: ECOSAR v0.99e
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Remark : Chemical may not be soluble enough to measure this predicted
Reliability : (2) valid with restrictions

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Type : semistatic
Species : Oncorhynchus mykiss (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l

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NOEC : 2.69
LC50 : 9.1
Limit test :
Analytical monitoring : yes
Method : OECD Guide-line 203 "Fish, Acute Toxicity Test"
Year : 2004
GLP : yes
Test substance : other TS:Cure-Rite® 18, purity: 98.5%

Remark : Following preliminary range-finding tests, fish were exposed, in groups of ten, to an aqueous solution of the test material over a range of concentrations of 2.6, 4.6, 8.2, 14.6 and 26 mg/l for a period of 96 hours at a temperature of approximately 14 C under semi-static test conditions. The test material solutions were prepared by stirring an excess (200 mg/l) of test material in dechlorinated tap water at approximately 2000 rpm at a temperature of approximately 14°C for 24 hours prior to removing any undissolved test material by filtration (0.2 µm) through a pre-conditioned filter to produce a saturated solution which had a nominal test concentration of 81 mg/l (Concentration determined by chemical analysis of a saturated solution prepared for preliminary analysis). This was then further diluted, as necessary, to produce the necessary test concentrations. The number of mortalities and any sub-lethal effects of exposure in each test and control vessel were determined 3 and 6 hours after the start of exposure and then daily throughout the test until termination after 96 hours.

Reliability : (1) valid without restriction

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4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type :
Species : Daphnia magna (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
NOEC : .37 measured/nominal
EC50 : 1.6 measured/nominal
Analytical monitoring : yes
Method : OECD Guide-line 202
Year : 2004
GLP : yes
Test substance : other TS:Cure-Rite® 18, purity: 98.5%

Remark : Following a preliminary range-finding test, twenty daphnids (2 replicates of 10 animals) were exposed to an aqueous solution of the test material at concentrations of 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6 and 10 mg/l for 48 hours at a temperature of approximately 21 C under static test conditions. The test material solutions were prepared by stirring an excess (200 mg/l) of test material in reconstituted water at approximately 2000 rpm at a temperature of 21°C for 24 hours prior to removing any undissolved test material by filtration (0.2 µm) through a pre-conditioned filter to produce a saturated solution which had a nominal test concentration of 147 mg/l (Concentration determined by chemical analysis of a saturated solution prepared for the range-finding test. This was then further diluted, as necessary, to produce the necessary test concentrations. The number of immobilised Daphnia were recorded after 24 and 48 hours. The 48-Hour EC50 for the test material to Daphnia magna based on nominal test concentrations was 2.0 mg/l with 95% confidence limits of 1.7 - 2.4 mg/l. The No Observed Effect Concentration was 0.56 mg/l. The nominal test concentrations were based on the results of preliminary chemical analysis of a saturated solution which showed a measured concentration of 147 mg/l. Analysis of the test preparations at 0 hours

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showed measured test concentrations to range from 68% to 85% of nominal. After 48 hours there was no significant decline in measured test concentrations with analysis of the 48 hours test preparations showing measured test concentrations of 53% to 90% of nominal. Given that some variation in the concentration of the saturated solution can be expected and hence some variation in measured test concentrations compared to the theoretical nominal concentrations, it was considered appropriate to calculate the results based on measured test concentrations. There was no significant decline in the measured test concentrations over the 48-Hour test period which was in-line with the stability analyses performed, therefore it was considered appropriate to base the results of the test on the mean measured test concentrations. The mean measured test concentrations were calculated to be 0.084, 0.144, 0.264, 0.373, 0.730, 1.46, 2.63, 4.34 and 7.92 mg/l. Based on the mean measured test concentrations the 48-Hour EC50 value was 1.6 mg/l with 95% confidence limits of 1.3 - 1.9 mg/l. The No Observed Effect Concentration at 48 hours was 0.37 mg/l.

Reliability : (1) valid without restriction
22.06.2005 (17)

Type : other: calculation
Species : Daphnia sp. (Crustacea)
Exposure period : 16 day(s)
Unit : mg/l
EC50 : 1121
Analytical monitoring : no
Method : other: ECOSAR v0.99e
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Remark : Chemical may not be soluble enough to measure this predicted effect.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
25.04.2001 (14)

Type : other: calculation
Species : Daphnia sp. (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
LC50 : 75767
Analytical monitoring : no
Method : other: ECOSAR v0.99e
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Remark : Chemical may not be soluble enough to measure this predicted effect.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
25.04.2001 (14)

Type : other: calculation
Species : Mysidopsis bahia (Crustacea)
Exposure period : 96 hour(s)
Unit : mg/l
EC50 : 188000
Analytical monitoring : no
Method : other: ECOSAR v0.99e

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Year : 1999
GLP : no
Test substance : other TS:molecular structure

Remark : Chemical may not be soluble enough to measure this predicted effect.
Reliability : (2) valid with restrictions
21.06.2005

(14)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species : Scenedesmus subspicatus (Algae)
Endpoint : growth rate
Exposure period : 72 hour(s)
Unit : mg/l
NOEC : 2.48
EC50 : 9.8 measured/nominal
Limit test :
Analytical monitoring : yes
Method : OECD Guide-line 201 "Algae, Growth Inhibition Test"
Year : 2004
GLP : yes
Test substance : other TS:Cure-Rite® 18, purity: 98.5%

Remark : Following a preliminary range-finding test, Scenedesmus subspicatus was exposed to an aqueous solution of the test material at concentrations of 4.2, 9.2, 18, 35 and 67 mg/l (three replicate flasks per concentration) for 72 hours, under constant illumination and shaking at a temperature of 24 ± 1 °C. The test material solutions were prepared by stirring an excess (200 mg/l) of test material in culture medium at approximately 2000 rpm at a temperature of approximately 21°C for 24 hours prior to removing any undissolved test material by filtration (0.2 µm) through a pre-conditioned filter to produce a saturated solution. This was then diluted, as necessary, to prepare the remaining test groups. Samples of the algal populations were removed daily and cell concentrations determined for each control and treatment group, using a Coulter® Multisizer Particle Counter. Exposure of Scenedesmus subspicatus to the test material gave an EbC50 (72 h) value based on biomass (cells/ml) of 14 mg/l; 95% confidence limits 12 - 16 mg/l, an EaC50 (72 h) value based on area under the growth curve of 17 mg/l; 95% confidence limits 14 - 20 mg/l and an ErC50 (0 - 72 h) value of 36 mg/l (It was not possible to calculate 95% confidence limits for the ErC50 value as the data generated did not fit the models available for the calculation of confidence limits. The No Observed Effect Concentration based on area under the growth curve and biomass (cells/ml) was 4.2 mg/l. Chemical analysis of the saturated solution at 0 hours showed the measured concentration to be 103 mg/l. Analysis of the test solutions at 0 hours showed the measured concentrations to be 4.23, 9.24, 18.4, 34.9 and 67.4 mg/l. Given that some variation in the concentration of the saturated solution can be expected and hence some variation in measured test concentrations compared to the theoretical nominal concentrations, it was considered appropriate to assign the nominal test concentrations on the 0-Hour measured test concentrations of 4.2, 9.2, 18, 35 and 67 mg/l. Analysis of the 72-Hour test solutions showed a marked decline in measured test concentration with values in the range of less than the limit of quantitation (LOQ) to 2.70 mg/l. The decline in measured test concentrations showed a concentration dependent effect with the higher concentrations exhibiting the greater percentage losses. The stability analysis performed showed the test material to be unstable in light conditions. Therefore it was considered that the greater losses of test material at the higher concentrations was due to inhibition of algal growth resulting in greater exposure to high light intensities. Whereas at the lower

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concentrations algal growth was greater and thus light intensity reduced. Given this decline in measured test concentrations it was considered justifiable to base the results on the geometric mean measured test concentrations in order to give a "worst case" analysis of the data. The EbC50 (72 h) based on biomass (cells/ml) was 5.9 mg/l; 95% confidence limits 5.4 - 6.4 mg/l. The EaC50 (72 h) based on area under the growth curve was 6.6 mg/l; 95% confidence limits 6.0 - 7.3 mg/l and the ErC50 (0 - 72 h) was 9.8 mg/l. The No Observed Effect Concentration based on area under the growth curve and biomass (cells/ml) was 2.48 mg/l.

Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
22.06.2005

(18)

Species : other algae: green algae
Endpoint : growth rate
Exposure period : 96 hour(s)
Unit : mg/l
EC50 : 40223
ChV : 779
Limit test :
Analytical monitoring : no
Method : other: ECOSAR v0.99e
Year :
GLP : no
Test substance : other TS: molecular structure

Remark : Chemical may not be soluble enough to measure this predicted effect.
Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
25.04.2001

(14)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

Species : other: fish
Endpoint : other
Exposure period : 30 day(s)
Unit : mg/l
ChV : 7012
Analytical monitoring : no
Method : other: ECOSAR v0.99e
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Remark : Chemical may not be soluble enough to measure this predicted effect.
Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
25.04.2001

(14)

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS**4.6.2 TOXICITY TO TERRESTRIAL PLANTS****4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS**

Type : other: calculation
Species : Eisenia fetida (Worm (Annelida), soil dwelling)
Endpoint : mortality
Exposure period : 14 day(s)
Unit : other: ppm
LC50 : 11449
Method : other: ECOSAR v0.99e
Year : 1999
GLP : no
Test substance : other TS: molecular structure

Remark : Chemical may not be soluble enough to measure this predicted effect.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
25.04.2001

(14)

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES**4.7 BIOLOGICAL EFFECTS MONITORING****4.8 BIOTRANSFORMATION AND KINETICS****4.9 ADDITIONAL REMARKS**

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

Type : LD50
Value : 5200 mg/kg bw
Species : rat
Strain : Sprague-Dawley
Sex : male/female
Number of animals :
Vehicle : other:corn oil
Doses :
Method : other: 40CFR Part 163.81-1
Year : 1980
GLP : yes
Test substance : other TS: Cure-Rite® 18, purity: not noted

Remark : Groups of albino rats (5 males/group) were administered doses of 1800, 2700, 4050, 6075, or 9112 mg/kg by gavage as a 50% suspension in corn oil. All animals were observed closely for signs of systemic toxicity and mortality at frequent intervals during the day of dosing and daily thereafter for 14 days. Gross necropsies were performed on the animals that died. At the end of the 14-day post exposure observation period the surviving animals were weighed, sacrificed, and subjected to gross necropsies.

Source : Discriminating dose: LD0 = 2,700 mg/kg
American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (1) valid without restriction
GLP study, Meets National Standards Method
Flag : Critical study for SIDS endpoint

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(2)

Type : LD50
Value : 9000 mg/kg bw
Species : mouse
Strain : CD-1
Sex : male/female
Number of animals :
Vehicle : other: corn oil
Doses :
Method : other: 40CFR Part 163.81-1
Year : 1980
GLP : yes
Test substance : other TS: Cure-Rite® 18; purity: not noted

Remark : Groups of albino rats (5 males/group) were administered doses of 25, 50, 100, 1800, 2700, 4050, 6075, or 9112 mg/kg by gavage as a 50% suspension in corn oil. All animals were observed closely for signs of systemic toxicity and mortality at frequent intervals during the day of dosing and daily thereafter for 14 days. Gross necropsies were performed on the animals that died. At the end of the 14-day post exposure observation period the surviving animals were weighed, sacrificed, and subjected to gross necropsies.

Discriminating dose: LD0 = 4,050 mg/kg
LD50 (95% conf. Limits) = 11,000 mg/kg (5,100-16,900 mg/kg)
for males and 7,000 mg/kg (4,900-9,100 mg/kg) for females

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Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (1) valid without restriction
GLP study, Meets National Standards Method
Flag : Critical study for SIDS endpoint
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Type : LD50
Value : 5110 mg/kg bw
Species : rat
Strain : other:Unknown
Sex : male
Number of animals : 25
Vehicle : other:corn oil
Doses :
Method : other: Federal Hazardous Substances Act (Revised, Fed. Reg., September 17, 1964
Year : 1971
GLP : no
Test substance : other TS: Good-Rite® 3030x18 (Cure-Rite® 18) ; purity: not noted

Remark : Groups of albino rats (5 males/group) were administered doses of 464, 1000, 2150, 4640, and 10,000 mg/kg by gavage as a 50% suspension in corn oil. All animals were observed closely for signs of systemic toxicity and mortality at frequent intervals during the day of dosing and at least once daily thereafter for 14 days. Gross necropsies were performed on the animals that died. At the end of the 14-day post exposure observation period the surviving animals were weighed, sacrificed, and subjected to gross necropsies.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
21.06.2005 (5)

Type : LD50
Value : 5000 mg/kg bw
Species : rat
Strain : Sprague-Dawley
Sex : male/female
Number of animals :
Vehicle : other:corn oil
Doses :
Method : other: 40CFR Part 163.81-1
Year : 1980
GLP : yes
Test substance : other TS: Cure-Rite® 18; purity: not noted

Remark : Groups of albino rats (5 males/group) were administered doses of 1800, 2700, 4050, 6075, or 9112 mg/kg by gavage as a 50% suspension in corn oil. All animals were observed closely for signs of systemic toxicity and mortality at frequent intervals during the day of dosing and daily thereafter for 14 days. Gross necropsies were performed on the animals that died. At the end of the 14-day post exposure observation period the surviving animals were weighed, sacrificed, and subjected to gross necropsies.

Source : Rat/CD® Sprague-Dawley (Taconic Farms)
Discriminating dose: LD0 = 2,700 mg/kg
Reliability : American Chemistry Council Rubber and Plastic Additives Panel
(1) valid without restriction
GLP study, Meets National Standards Method
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5.1.2 ACUTE INHALATION TOXICITY

Type : LC0
Value : 164.4 mg/l
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Exposure time : 1 hour(s)
Method : other: Federal Hazardous Substances Act (Revised, Fed. Reg., September 17, 1964)
Year : 1971
GLP : no
Test substance : other TS: Good-Rite® 3030x18 (Cure-Rite® 18); purity: not noted

Remark : A group of 10 male albino rats were exposed to 164.4 mg/l (calculated) for 1 hour. All animals were observed closely for signs of systemic toxicity and mortality during the exposure period and at frequent intervals daily thereafter for 14 days. At the end of the 14-day post exposure observation period the surviving animals were weighed, sacrificed, and subjected to gross necropsies.

No evidence of systemic toxicity or mortality was observed.

Test substances measured not analysed.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (1) valid without restriction
GLP study, Meets National Standards Method
Flag : Critical study for SIDS endpoint
22.06.2005 (5)

5.1.3 ACUTE DERMAL TOXICITY

Type : LD50
Value : > 10000 mg/kg bw
Species : rabbit
Strain :
Sex : male/female
Number of animals :
Vehicle :
Doses :
Method : other:) Federal Hazardous Substances Act (Revised, Fed. Reg., September 17, 1964)
Year : 1971
GLP : no
Test substance : other TS: Good-Rite® 3030x18 (Cure-Rite® 18); purity: not noted

Remark : Groups of albino rabbits (2/sex/group) were administered doses of 1000, 2150, 4640, and 10,000 mg/kg to the abraded and intact skin and then wrapped with a semi-occlusive bandage. After 24 hours the bandages were removed. All animals were observed closely for signs of systemic toxicity and mortality, and irritation. Examinations for gross signs of toxicity and dermal irritation were conducted at frequent intervals during the 14 day post exposure period. Gross necropsies were performed on the animal (1,000 mg/kg group) that died. At the end of the 14-day post exposure observation period the surviving animals were weighed, sacrificed, and subjected to gross necropsies.

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Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (1) valid without restriction
GLP study, Meets National Standards Method
Flag : Critical study for SIDS endpoint
21.06.2005 (5)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

Species : rabbit
Concentration :
Dose :
Exposure time :
Comment :
Number of animals :
Vehicle :
Result : irritating
Classification :
Method : other: Federal Hazardous Substances Act (Revised, Fed. Reg., September 17, 1964)
Year : 1971
GLP : no
Test substance : other TS: Good-Rite® 3030x18 (Cure-Rite® 18); purity: not noted
Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (1) valid without restriction
GLP study, Meets National Standards Method
22.06.2005 (5)

Species : rabbit
Concentration :
Dose :
Exposure time :
Comment :
Number of animals :
Vehicle :
Result : not irritating
Classification :
Method : other: Section 1500.42, Federal Hazardous Substances Act Regulations, CFR 16, p. 125
Year : 1981
GLP : yes
Test substance : other TS: Cure-Rite® 18; purity: not noted
Result : No positive scores; one animal had scores of "1" for redness and chemosis at day one.
Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (1) valid without restriction
GLP study, Meets National Standards Method
21.06.2005 (4)

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

Type	: 7.1
Species	: rat
Sex	: male/female
Strain	: Sprague-Dawley
Route of admin.	: oral feed
Exposure period	: 2 years
Frequency of treatm.	: continuous daily
Post exposure period	: none
Doses	: 0, 20, 60, 200, or 600 ppm
Control group	: yes, concurrent no treatment
NOAEL	: 200 ppm
LOAEL	: 600 ppm
Method	: EPA OPP 82-5
Year	: 1986
GLP	: yes
Test substance	: other TS: Commercial Cure-Rite® 18; purity: 96.8%
Result	<p>: Diets containing 0, 20, 60, or 600 ppm of the test material were administered to groups (60/sex/group) of Sprague-Dawley rats for 112 weeks. Ten rats/sex/group were identified for a 12 month interim sacrifice. Animals were checked twice daily for mortality and gross signs of toxicity. A detailed physical exam palpation for tissue masses was performed weekly. Body weight and feed consumption were measured weekly through week 12 and biweekly from week 13 to 26 and monthly thereafter. Hematology, clinical chemistry, and urinalysis were conducted pretest on 15 animals/sex and at months 6, 12, 18, and 24. Animals were given a complete gross post mortem examination following spontaneous death, death in extremis, or scheduled sacrifices. A full set of organs were subjected to gross and histological examination. All tissues from the control and high dose were processed for pathological examination at 12 months and termination. Tissues in mid and low dose groups were identified for pathological evaluation based on the pathological evaluations in the controls and high dose groups. Organs also were weighed. Furthermore, the testes from 3 of the 10 males at 12 months were processed for electron and light microscopy examination. Statistical analyses were conducted on the end points.</p> <p>A compound related increase in tumors of the urinary system was observed in the high dose group: males (kidney: urothelia carcinoma, 2/60; squamous cell carcinoma, 1/60; ureters: urothelial carcinoma 4/6 [2 in one male]; urinary bladder: urothelial papilloma, 3/59; urothelial carcinoma, 4/59; squamous cell papilloma, 1/59; squamous cell carcinoma, 2/59; combined total neoplasms: 17 vs 1 urothelial papilloma in the control); females (kidney: urothelial papilloma, 1/60; urothelia carcinoma, 3/60; squamous cell carcinoma, 3/60; ureters: urothelial carcinoma 2/8; urinary bladder: urothelial papilloma, 3/59; urothelial carcinoma, 2/59; squamous cell papilloma, 2/59; squamous cell carcinoma, 1/59; combined total neoplasms: 15 vs 0 in the control). Tumors of the urinary system were not found in the mid and low dose groups. Ureters were not evaluated in the controls, low or mid dose groups.</p> <p>Kidney weights, non-neoplastic urinary tract abnormalities, and rales was observed in the high dose males and females. Body weights also were significantly lower in the high dose males and females. No compound-related effects on hematology, clinical chemistry, or urinalysis were noted.</p>

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
 21.06.2005

(8)

5.5 GENETIC TOXICITY 'IN VITRO'

Type : Bacterial reverse mutation assay
System of testing : Salmonella typhimurium strains TA-1535, TA-1537, TA-1538, TA-98, TA-100
Test concentration : 0.5 to 1,000 ug/plate
Cycotoxic concentr. : With metabolic activation: 0.5 to 100 ug/plate (little to no toxicity)
 Without metabolic activation: 0.5 to 100 ug/plate (little to no toxicity)
Metabolic activation : with and without
Result : negative
Method :
Year : 1975
GLP : no data
Test substance : other TS: Commercial Cure-Rite® 18 (Purified); purity: 97.5%

Method : Ames et al (1975) Mutation Res. 31:347-364; McCann et al. (1975) Proc. Nat. Acad. Sci. 72:5135-5139

Remark : The test compound was evaluated for genetic activity in microbial assays with and without the addition of mammalian metabolic activation preparations. The methods are described in Hinderer et al., 1983 as follows:

"Salmonella typhimurium strains TA-1535, TA-1537, TA-1538, TA-98 and TA-100 were obtained from Dr. Bruce Ames. All indicator strains were kept at 4°C on minimal medium plates supplemented with a trace of biotin and an excess of histidine (Ames, 1980). In addition, the plates with the plasmid-carrying Salmonella strains (TA-98 and TA-100) were supplemented with 26µg/ml of ampicillin to ensure stable maintenance of the plasmid pKM101."

"The bacterial strains were cultured at 37°C in Oxid Media #2 (nutrient broth), and Vogel Bonner Medium E with 2% glucose was used as the selective medium (Vogel and Bonner, 1956). The overlay agar was prepared according to the method of Ames et al (1975). S-9 liver homogenates, which were prepared from Aroclor 1254-induced and noninduced adult Sprague-Dawley male rats as described by Ames et al (1975, were prepared from Bionetics Laboratory Products, Litton Bionetics, Inc. An S-9 mix was prepared by adding the following ingredients per milliliter of mix: 4 µmoles NADP (sodium salt), 5 µmoles D-glucose-6-phosphate, 8 µmoles MgCl₂, 33 µmoles KCl, 100 µmoles sodium phosphate buffer (pH 7.4), and 100 µl of rat liver S-9 fraction."

"All tests were based on the methods of Ames et al (1975). Test compounds were dissolved in dimethylsulfoxide (DMSO). Solvent and positive controls were used as listed in Table II." (Table II is summarized as follows: Positive controls for the non-activation assays were 1 ug/plate sodium azide for TA-1535 and TA-100, 50 ug/plate 9-aminoacridine for TA-1537, 10 µg 2-nitrofluorene for TA-1538 and TA-98. The positive control used for the activation assays was 2.5 ug/plate 2-anthramine.) "The highest dose was established as one which produced some toxicity."

"Criteria which were used to determine whether a chemical was mutagenic were: 1) an increase in revertants in strains TA-1535, TA-1537, TA-1538 of three times the solvent control; 2) an increase in revertants in strains TA-98 and TA-100 of twice the solvent control; 3) reproducibility; and 4) a dose-

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related response, and a consistent pattern of response between strains derived from the same parental strain ----."

Source Reliability	: Signed QA assurance statement provided : American Chemistry Council Rubber and Plastic Additives Panel : (2) valid with restrictions Meets generally accepted scientific standards, well documented and acceptable for assessment.
Flag 21.06.2005	: Critical study for SIDS endpoint (6) (10)
Type	: Bacterial reverse mutation assay
System of testing	: Escherichia coli strain WP2uvrA-
Test concentration	: 0.5 to 1,000 ug/plate
Cycotoxic concentr.	: With metabolic activation: 0.5 to 100 ug/plate (little to no toxicity) Without metabolic activation: 0.5 to 100 ug/plate (little to no toxicity)
Metabolic activation	: with and without
Result	: negative
Method	:
Year	:
GLP	:
Test substance	: other TS: Cure-Rite® 18 (purified), purity: 97.5%
Method	: Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215
Remark	: "The E. coli strain WP2 uvrA- was obtained from Dr. M.H.L. Green, MRC Cell Mutation Unit, University of Sussex, England. The indicator strain was kept at 4°C on standard methods agar plates or minimal medium plates supplemented with an excess triptophan. Laboratory cultures were grown at 37°C in Oxoid #2 (nutrient broth). Vogel Bonner medium E (Vogel and Bonner, 1956) with 2% glucose was used as the selective medium. The overlay agar was prepared according to the method of Green and Murie. (1976). The S-9 activation system was prepared as described for the Salmonella plate assay. The procedures were based on a modification of the methods described by Ames et al (1975)."
	DMSO was also used as the solvent to dissolve the test material. For the nonactivation test 10 µg of methyl nitrosoguanidine was the positive control. For the activation test 2.5 µg of 2-(2-furyl)-3-(5-nitro-2-furyl)-acrylamide was the positive control.
	"A chemical was considered mutagenic if there was a dose-related response over a minimum of three test concentrations."
	The test compound did not demonstrate mutagenic activity in any of the assays conducted and was considered not mutagenic under the test conditions.
Source Reliability	: A signed QA assurance statement was provided. : American Chemistry Council Rubber and Plastic Additives Panel : (2) valid with restrictions Meets generally accepted scientific standards, well documented and acceptable for assessment.
Flag 21.06.2005	: Critical study for SIDS endpoint (6) (10)
Type	: Cytogenetic assay
System of testing	: Chinese Hamster Ovary (CHO) Cells
Test concentration	: 2.500 to 20.000 ug/ml
Cycotoxic concentr.	: concentration used based on mouse lymphoma L5178Y cells
Metabolic activation	: with and without

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Result	: positive
Method	:
Year	: 1983
GLP	:
Test substance	: other TS: Cure-Rite® 18 (purified); purity = 97.5%.
Method	: Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215
Remark	: CHO cells were obtained from the American Culture Collection, Repository No. CCL61, Rockville, MD. CHO cells were grown in McCoy's 5a medium supplemented with 10% fetal calf serum, L-glutamine, and penicillin-streptomycin. Cultures were set up approximately 24 hours prior to treatment by seeding 8x10 ⁵ cells per 75-cm ² plastic flask in 10 ml of fresh medium. The test chemical were dissolved in DMSO. Untreated and solvent (1% final concentration) control cultures were used and the positive controls were triethylenemelamine (0.5, 0.75, or 1.0 µg/ml) without activation or cyclophosphamide (62.25, 130.5, or 261 µg/ml) with S-9 activation. The dose range was selected on the basis of survival of L5178Y cells 24 hours after treatment in the mouse lymphoma forward mutation assay, considering that the exposure period in the CHO assay (2 hours) is shorter than the mouse lymphoma assay (4 hours). The highest dose for cytogenetics assay was selected to produce little or no toxicity. In the nonactivation assay, approximately 2-3 x 10 ⁶ cells were treated with the test chemical for two hours at 37° C in growth medium. The exposure period was terminated by washing the cells twice with saline containing 10% FBS and then adding fresh medium. Incubation continued for 17 hours. Colcemid was added for the last two hours of incubation (2 x 10 ⁻⁷ M final concentration), and metaphase cells were collected by mitotic shake-off. The cells were treated with 0.075 M KCl hypotonic solution, washed three times in fixative (methanol:acetic acid, 3:1 v/v), dropped into slides, and air-dried. The slides were stained with 10% Giemsa at pH 6.8. Fifty or 100 cells were scored at each dose level. The activation assay differed from the nonactivation assay in that the S-9 reaction mixture (2.4 mg NADP, 4.5 mg isocitric acid and 15 µl S-9 fraction per ml) was added to the growth medium, together with the test chemical, for two hours. After exposure the cultures were treated as above. statistical evaluations were conducted using the Student t-test. Signed QA assurance statement provided
Source	: American Chemistry Council Rubber and Plastic Additives Panel
Reliability	: (2) valid with restrictions Meets generally accepted scientific standards, well documented and acceptable for assessment.
Flag	: Critical study for SIDS endpoint
21.06.2005	(6) (11)
Type	: DNA damage and repair assay
System of testing	: Escherichia coli strains W3110 (pol A+) and W3078 (pol A-)
Test concentration	: 100 to 5,000 µg/plate
Cycotoxic concentr.	: With metabolic activation: 0.5 to 100 µg/plate (little or no toxicity) Without metabolic activation: 0.5 to 100 µg/plate (little or no toxicity)
Metabolic activation	: with and without
Result	: positive
Method	:

5. Toxicity

Id 13752-51-7

Date 08.09.2005

Year : 1983
GLP :
Test substance : other TS: Cure-Rite® 18.(purified); purity: 97.5%

Method : Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215

Remark : Repair competent E. coli strain W3110 (polA+) and repair deficient strain E. coli p3078 (polA-) were obtained from Dr. RosenKrantz, Columbia University, New York. The indicator strains were kept at 4°C on standard methods agar plates or HA + T medium. For each experiment, the bacterial strains were cultured overnight at 37°C in HA + T medium without agar. A thymine-supplemented HA agar was used as the selective medium.

The procedure was based on the method of Slater et al. (1971). Test material was dissolved in DMSO. Positive controls (10 µl methylmethane sulfonate without S-9 and 100µl dimethylnitrosamine with S-9) and solvent controls (50 µl DMSO) were used. In order, 2.0 ml of HA + T overlay agar and 0.1 ml - 0.2 ml of indicator organisms were added to a sterile test tube in a 45°C water bath. Equal volumes of at least 4 doses of the test material and a single dose of the control chemicals were added to wells of uniform diameter in the agar in the appropriate plates. For noactivation assays. 0.05 ml of phosphate buffer, pH 7.4 was added to each well. For activation assays, 0.05 of the S-9 mix was added. The plates were incubated at 37°C for approximately 24 hours. The zones of inhibition were measured and recorded in millimeters.

A differential of 4 mm or greater between the competent and noncompetent strains was considered to have produced a DNA-modifying effect. If no zones were induced, the results were considered to be a no-test. Additional criteria such as reproducibility also were considered.

Source : Signed QA assurance statement provided
Reliability : American Chemistry Council Rubber and Plastic Additives Panel
(2) valid with restrictions
Meets generally accepted scientific standards, well documented and acceptable for assessment.

Flag : Critical study for SIDS endpoint

21.06.2005

(6) (10)

Type : Mammalian cell gene mutation assay
System of testing : BALB 3T3 Mouse Cells
Test concentration : 0.01000 to 0.20000 ug/ml
Cycotoxic concentr. : 0.488 ug/ml
Metabolic activation : without
Result : positive
Method :
Year : 1983
GLP :
Test substance : other TS: Cure-Rite® 18 (purified); purity = 97.5%.

Method : Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215

Remark : Clone 113 of BALB/3T3 mouse cells was obtained from Dr. Takeo Kakunga, NCI, Bethesda, MD. Subclones that were selected for low spontaneous frequencies of foci formation were used. Stocks were maintained in liquid nitrogen, and laboratory cultures were checked periodically for mycoplasma contamination. Cultures were grown and passed weekly in Eagle's Minimum Essential Medium (EMEM) supplemented with 10% fetal bovine serum.

The test chemical was dissolved in a small quantity of DMSO and then

diluted with EMEM so the final concentration of DMSO was less than 0.5%. Lower concentrations were obtained by serial dilutions with EMEM. The dose range was based on the results of a clonal toxicity assay in which a series of 200 cells/dish were exposed in triplicate to a wide range of test chemical concentrations for 3 days. Five doses were selected to cover a wide range of toxicities from little or no reduction in colony-forming ability to a 50% reduction in the colony number. A negative control consisting of cells exposed to 0.5% DMSO in EMEM and a positive control treatment of 5 µg/ml 3-methylcholanthrene (3-MCA) were also employed.

The transformation assay was based on the method of Kakunga (1973). Twenty four hours prior to treatment, a series of 25-cm² flasks was seeded with 104 cells/flask and incubated. Fifteen flasks then were treated for each test dose, positive control, and negative control. The flasks were incubated for a three-day period at 37°C in a humidified atmosphere containing 5% CO₂. The cells were then washed, and the incubation was continued for 4 weeks with refeeding twice a week. The assay was terminated by fixing the cell monolayers with methanol and staining Giemsa. The stained flasks were examined by eye and by microscope to determine the number of foci of transformed cells. The foci consisted of piled up and randomly oriented cells, sometimes with necrotic centers, on surrounding monolayers of normal cells.

Statistical tables provided by Kastenbaum and Bowman (1970) were used to determine statistical significance.

Precipitation conc: >250 µg/ml

Signed QA assurance statement provided.

**Source
Reliability**

- : American Chemistry Council Rubber and Plastic Additives Panel
- : (2) valid with restrictions
- Meets generally accepted scientific standards, well documented and acceptable for assessment.

Flag
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- : Critical study for SIDS endpoint

(6) (12)

**Type
System of testing
Test concentration
Cytotoxic concentr.**

- : Mouse lymphoma assay
- : Mouse Lymphoma cell line L5178Y TK+/-
- : 1.250 to 25.0 µg/ml
- : With metabolic activation: Percent relative growth was 64.9% at 1.560 µg/ml and 5.2% at 25.0 µg/ml
- Without metabolic activation: Percent relative growth was 29.7% at 1.250 µg/ml and 7.7-11.2% at 5.0-20.0 µg/ml

**Metabolic activation
Result
Method
Year
GLP
Test substance**

- : with and without
- : positive
- :
- : 1983
- :
- : other TS: Cure-Rite® 18 (purified); purity = 97.5%.

Method

- : Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C. Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215

Remark

- : Mouse Lymphoma cells (L5178Y TK+/-, clone 3.7.2C derived from the Fischer line from Dr. Donald Clive) were treated with doses of 0, 1.25, 5, 15, and 20 µg/ml. The negative solvent control was prepared by adding 0.1 DMSO per 10 ml of culture. The positive control was 0.5 µl/ml ethyl methanesulfonate under nonactivation conditions and) and 0.3 µl/ml dimethylnitrosamine under activation conditions. The assay procedure was very similar to the method of Clive and Spector (1975). Each treated culture consisted of 3x10⁶ cells suspended in 10 ml final volumes in 15 ml centrifuge tubes. Nonactivation and activation assays were conducted the same except the cell cultures in the activation assay contained the S-9,

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Aroclor 1254-induced liver preparation with cofactors. The cells were exposed to the test material dose for 4 hours, were washed, and were allowed an expression time of two days in growth medium. At the end of the expression period, 3×10^6 cells from each treated culture were seeded in the selection medium (1×10^6 cells per 100 mm dish). Cloning efficiency was determined by serially diluting a portion of the cells and seeding 300 cells in the nonselective cloning medium at 100 cells per 100 mm dish. BrdUrd-resistant colonies (TK^{-/-} mutants) and viable colonies (nonselective medium) were counted after 10 days incubation at 37°C in a humidified atmosphere containing 5% CO₂. The ratio of resistant to viable colonies yielded the mutant frequency in units of 10^{-4} . The average of the solvent and untreated negative control mutant frequencies was used as the background or spontaneous mutant frequency for each trial. A treated culture was considered to have a significantly elevated mutation frequency if the frequency exceeded 10×10^{-6} plus 1.5 times the background frequency. Additional criteria such as a dose or toxicity related response and repeatability between trial were also used to determine the presence of mutagenic activity.

The test substance was positive with and without activation but only at doses that were very toxic.

Precipitation conc: >250 ug/ml

Signed QA assurance statement provided.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
Meets generally accepted scientific standards, well documented and acceptable for assessment.

Flag : Critical study for SIDS endpoint

22.06.2005

(6) (10)

Type : Bacterial reverse mutation assay
System of testing : Salmonella typhimurium strains TA-1535, TA-1537, TA-1538, TA-98, TA-100

Test concentration : 0.5 to 5,000 ug/plate
Cycotoxic concentr. : With metabolic activation: 0.5 to 100 ug/plate (little to no toxicity)
Without metabolic activation: 0.5 to 100 ug/plate (little to no toxicity)

Metabolic activation : with and without
Result : negative

Method :

Year : 1975

GLP :

Test substance : other TS: Commercial Cure-Rite® 18, purity: 95.6%

Method : Ames et al (1975) Mutation Res. 31:347-364;
McCann et al. (1975) Proc. Nat. Acad. Sci. 72:5135-5139

Remark : The test compound was evaluated for genetic activity in microbial assays with and without the addition of mammalian metabolic activation preparations. The methods are described in Hinderer et al., 1983 as follows:
"Salmonella typhimurium strains TA-1535, TA-1537, TA-1538, TA-98 and TA-100 were obtained from Dr. Bruce Ames. All indicator strains were kept at 4°C on minimal medium plates supplemented with a trace of biotin and an excess of histidine (Ames, 1980). In addition, the plates with the plasmid-carrying Salmonella strains (TA-98 and TA-100) were supplemented with 26 µg/ml of ampicillin to ensure stable maintenance of the plasmid pKM101."

"The bacterial strains were cultured at 37°C in Oxid Media #2 (nutrient broth), and Vogel Bonner Medium E with 2% glucose was used as the selective medium (Vogel and Bonner, 1956). The overlay agar was prepared according to the method of Ames et al (1975). S-9 liver

homogenates, which were prepared from Aroclor 1254-induced and noninduced adult Sprague-Dawley male rats as described by Ames et al (1975, were prepared from Binetics Laboratory Products, Litton Bionetics, Inc. An S-9 mix was prepared by adding the following ingredients per milliliter of mix: 4 µmoles NADP (sodium salt), 5 µmoles D-glucose-6-phosphate, 8 µmoles MgCL₂, 33 µmoles KCL, 100 µmoles sodium phosphate buffer (pH 7.4), and 100 µl of rat liver S-9 fraction."

"All tests were based on the methods of Ames et al (1975). Test compounds were dissolved in dimethylsulfoxide (DMSO). Solvent and positive controls were used as listed in Table II." (Table II is summarized as follows: Positive controls for the non-activation assays were 1 ug/plate sodium azide for TA-1535 and TA-100, 50 ug/plate 9-aminoacridine for TA-1537, 10 µg 2-nitrofluorene for TA-1538 and TA-98. The positive control used for the activation assays was 2.5 ug/plate 2-anthramine.) "The highest dose was established as one which produced some toxicity."

"Criteria which were used to determine whether a chemical was mutagenic were: 1) an increase in revertants in strains TA-1535, TA-1537, TA-1538 of three times the solvent control; 2) an increase in revertants in strains TA-98 and TA-100 of twice the solvent control; 3) reproducibility; and 4) a dose-related response, and a consistent pattern of response between strains derived from the same parental strain ----."

Signed QA assurance statement provided

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
 Meets generally accepted scientific standards, well documented and acceptable for assessment.

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(6) (10)

Type : Bacterial reverse mutation assay
System of testing : Salmonella typhimurium strains TA-1535, TA-1537, TA-1538, TA-98, TA-100 and Saccharomyces strain D4
Test concentration : 0.5 to 1,000 ug/plate
Cycotoxic concentr. : With metabolic activation: 1000 ug/plate (TA-98); 1000 ug/plate, 500 ug/plate, and 100 ug/plate (D4)
 Without metabolic activation: 1000 ug/plate (TA-98); 1000 ug/plate, 500 ug/plate, and 100 ug/plate (D4)
Metabolic activation : with and without
Result : negative
Method :
Year : 1975
GLP :
Test substance : other TS: Commercial Cure-Rite® 18; purity: not noted

Method : Ames et al (1975) Mutation Res. 31:347-364; McCann et al. (1975) Proc. Nat. Acad. Sci. 72:5135-5139

Remark : The test compound was evaluated for genetic activity in microbial assays with and without the addition of mammalian metabolic activation preparations. The methods are described in Hinderer et al., 1983 as follows:

"Salmonella typhimurium strains TA-1535, TA-1537, TA-1538, TA-98 and TA-100 were obtained from Dr. Bruce Ames. All indicator strains were kept at 4°C on minimal medium plates supplemented with a trace of biotin and an excess of histadine (Ames, 1980). In addition, the plates with the plasmid-carrying Salmonella strains (TA-98 and TA-100) were supplemented with 26µg/ml of ampicillin to ensure stable maintenance of the plasmid pKM101. "

"The bacterial strains were cultured at 37°C in Oxid Media #2 (nutrient

broth), and Vogel Bonner Medium E with 2% glucose was used as the selective medium (Vogel and Bonner, 1956). The overlay agar was prepared according to the method of Ames et al (1975). S-9 liver homogenates, which were prepared from Aroclor 1254-induced and noninduced adult Sprague-Dawley male rats as described by Ames et al (1975, were prepared from Binetics Laboratory Products, Litton Bionetics, Inc. An S-9 mix was prepared by adding the following ingredients per milliliter of mix: 4 µmoles NADP (sodium salt), 5 µmoles D-glucose-6-phosphate, 8 µmoles MgCL₂, 33 µmoles KCL, 100 µmoles sodium phosphate buffer (pH 7.4), and 100 µl of rat liver S-9 fraction."

"All tests were based on the methods of Ames et al (1975). Test compounds were dissolved in dimethylsulfoxide (DMSO). Solvent and positive controls were used as listed in Table II." (Table II is summarized as follows: Positive controls for the non-activation assays were 1 ug/plate sodium azide for TA-1535 and TA-100, 50 ug/plate 9-aminoacridine for TA-1537, 10 µg 2-nitrofluorene for TA-1538 and TA-98. The positive control used for the activation assays was 2.5 ug/plate 2-anthramine.) "The highest dose was established as one which produced some toxicity."

"Criteria which were used to determine whether a chemical was mutagenic were: 1) an increase in revertants in strains TA-1535, TA-1537, TA-1538 of three times the solvent control; 2) an increase in revertants in strains TA-98 and TA-100 of twice the solvent control; 3) reproducibility; and 4) a dose-related response, and a consistent pattern of response between strains derived from the same parental strain ----."

QA assurance statement provided.
Saccharomyces strain D4 not reported in referenced publication.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
Meets generally accepted scientific standards, well documented and acceptable for assessment.

Flag : Critical study for SIDS endpoint

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(6) (10)

Type : Bacterial reverse mutation assay
System of testing : Escherichia coli strain WP2uvrA
Test concentration : 0.5 to 1,000 ug/plate
Cycotoxic concentr. : With metabolic activation: 0.5 to 100 ug/plate (little or no toxicity) Without metabolic activation: 0.5 to 100 ug/plate (little or no toxicity)

Metabolic activation : with and without
Result : negative

Method :

Year : 1983

GLP :

Test substance : other TS: Commercial Cure-Rite® 18, purity: 95.6%

Method : Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215

Remark : "The E. coli strain WP2 uvrA- was obtained from Dr. M.H.L. Green, MRC Cell Mutation Unit, University of Sussex, England. The indicator strain was kept at 4°C on standard methods agar plates or minimal medium plates supplemented with an excess triptophan. Laboratory cultures were grown at 37°C in Oxoid #2 (nutrient broth). Vogel Bonner medium E (Vogel and Bonner, 1956) with 2% glucose was used as the selective medium. The overlay agar was prepared according to the method of Green and Murie. (1976). The S-9 activation system was prepared as described for the Salmonella plate assay. The procedures were based on a modification of the methods described by Ames et al (1975)."

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DMSO was also used as the solvent to dissolve the test material. For the nonactivation test 10 µg of methylnitrosoguanidine was the positive control. For the activation test 2.5 µg of 2-(2-furyl)-3-(5-nitro-2-furyl)-acrylamide was the positive control.

"A chemical was considered mutagenic if there was a dose-related response over a minimum of three test concentrations."

The test compound did not demonstrate mutagenic activity in any of the assays conducted and was considered not mutagenic under the test conditions.

Source	: Signed QA assurance statement provided
Reliability	: American Chemistry Council Rubber and Plastic Additives Panel
	: (2) valid with restrictions
	: Meets generally accepted scientific standards, well documented and acceptable for assessment.
Flag	: Critical study for SIDS endpoint
21.06.2005	(6) (10)
Type	: Cytogenetic assay
System of testing	: Chinese Hamster Ovary (CHO) Cells
Test concentration	: 0.313 to 5.000 µg/ml
Cycotoxic concentr.	: concentration used based on mouse lymphoma L5178Y cells
Metabolic activation	: with and without
Result	:
Method	:
Year	: 1983
GLP	:
Test substance	: other TS: Commercial Cure-Rite® 18; purity = 95.6%.
Method	: Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215
Remark	: CHO cells were obtained from the American Culture Collection, Repository No. CCL61, Rockville, MD. CHO cells were grown in McCoy's 5a medium supplemented with 10% fetal calf serum, L-glutamine, and penicillin-streptomycin. Cultures were set up approximately 24 hours prior to treatment by seeding 8x10 ⁵ cells per 75-cm ² plastic flask in 10 ml of fresh medium.

The test chemical were dissolved in DMSO. Untreated and solvent (1% final concentration) control cultures were used and the positive controls were triethylenemelamine (0.5, 0.75, or 1.0 µg/ml) without activation or cyclophosphamide (62.25, 130.5, or 261 µg/ml) with S-9 activation. The dose range was selected on the basis of survival of L5178Y cells 24 hours after treatment in the mouse lymphoma forward mutation assay, considering that the exposure period in the CHO assay (2 hours) is shorter than the mouse lymphoma assay (4 hours). The highest dose for cytogenetics assay was selected to produce little or no toxicity.

In the nonactivation assay, approximately 2-3 x 10⁶ cells were treated with the test chemical for two hours at 37° C in growth medium. The exposure period was terminated by washing the cells twice with saline containing 10% FBS and then adding fresh medium. Incubation continued for 17 hours. Colcemid was added for the last tow hours of incubation (2 x 10⁻⁷ M final concentration), and metaphase cells were collected by mitotic shake-off. The cells were treated with 0.075 M KCl hypotonic solution, washed three times in fixative (methanol:acetic acid, 3:1 v/v), dropped into slides, and air-dried. The slides were stained with 10% Giemsa at pH 6.8. Fifty or 100 cells were scored at each dose level.

The activation assay differed from the nonactivation assay in that the S-9

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reaction mixture (2.4 mg NADP, 4.5 mg isocitric acid and 15 µl S-9 fraction per ml) was added to the growth medium, together with the test chemical, for two hours. After exposure the cultures were treated as above.

Statistical evaluations were conducted using the Student t-test.

Result	: Signed QA assurance statement provided
	: Genotoxic effects:With metabolic activation: negative
	: Without metabolic activation: positive
Source	: American Chemistry Council Rubber and Plastic Additives Panel
Reliability	: (2) valid with restrictions
	: Meets generally accepted scientific standards, well documented and acceptable for assessment.
Flag	: Critical study for SIDS endpoint
21.06.2005	(6) (11)
Type	: DNA damage and repair assay
System of testing	: Escherichia coli strains W3110 (pol A+) and W3078 (pol A-)
Test concentration	: 100 to 5,000 ug/plate
Cycotoxic concentr.	: With metabolic activation: 0.5 to 100 ug/plate (little or no toxicity)Without metabolic activation: 0.5 to 100 ug/plate (little or no toxicity)
Metabolic activation	: with and without
Result	: positive
Method	:
Year	: 1983
GLP	:
Test substance	: other TS: Commercial Cure-Rite® 18, purity: 95.6%
Method	: Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215
Remark	: Repair competent E. coli strain W3110 (polA+) and repair deficient strain E. coli p3078 (polA-) were obtained from Dr. RosenKrantz, Columbia University, New York. The indicator strains were kept at 4°C on standard methods agar plates or HA + T medium. For each experiment, the bacterial strains were cultured overnight at 37°C in HA + T medium without agar. A thymine-supplemented HA agar was used as the selective medium.
	<p>The procedure was based on the method of Slater et al. (1971). Test material was dissolved in DMSO. Positive controls (10 µl methylmethane sulfonate without S-9 and 100µl dimethylnitrosamine with S-9) and solvent controls (50 µl DMSO) were used. In order, 2.0 ml of HA + T overlay agar and 0.1 ml - 0.2 ml of indicator organisms were added to a sterile test tube in a 45°C water bath. Equal volumes of at least 4 doses of the test material and a single dose of the control chemicals were added to wells of uniform diameter in the agar in the appropriate plates. For noactivation assays. 0.05 ml of phosphate buffer, pH 7.4 was added to each well. For activation assays, 0.05 of the S-9 mix was added. The plates were incubated at 37°C for approximately 24 hours. The zones of inhibition were measured and recorded in millimeters.</p> <p>A differential of 4 mm or greater between the competent and noncompetent strains was considered to have produced a DNA-modifying effect. If no zones were induced, the results were considered to be a no-test. Additional criteria such as reproducibility also were considered.</p>
Source	: Signed QA assurance statement provided
Reliability	: American Chemistry Council Rubber and Plastic Additives Panel
	: (2) valid with restrictions
	: Meets generally accepted scientific standards, well documented and acceptable for assessment.
Flag	: Critical study for SIDS endpoint

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(6) (10)

Type : Mammalian cell gene mutation assay
System of testing : BALB 3T3 Mouse Cells
Test concentration : 0.05000 to 0.10000 ug/ml
Cycotoxic concentr. : 0.488 ug/ml
Metabolic activation : without
Result : negative
Method :
Year : 1983
GLP :
Test substance : other TS: Commercial Cure-Rite® 18; purity = 95.6%.

Method : Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215

Remark : Clone 113 of BALB/3T3 mouse cells was obtained from Dr. Takeo Kakunga, NCI, Bethesda, MD. Subclones that were selected for low spontaneous frequencies of foci formation were used. Stocks were maintained in liquid nitrogen, and laboratory cultures were checked periodically for mycoplasma contamination. Cultures were grown and passed weekly in Eagle's Minimum Essential Medium (EMEM) supplemented with 10% fetal bovine serum.

The test chemical was dissolved in a small quantity of DMSO and then diluted with EMEM so the final concentration of DMSO was less than 0.5%. Lower concentrations were obtained by serial dilutions with EMEM. The dose range was based on the results of a clonal toxicity assay in which a series of 200 cells/dish were exposed in triplicate to a wide range of test chemical concentrations for 3 days. Five doses were selected to cover a wide range of toxicities from little or no reduction in colony-forming ability to a 50% reduction in the colony number. A negative control consisting of cells exposed to 0.5% DMSO in EMEM and a positive control treatment of 5µg/ml 3-methylcholanthrene (3-MCA) were also employed.

The transformation assay was based on the method of Kakunga (1973). Twenty four hours prior to treatment, a series of 25-cm² flasks was seeded with 104 cells/flask and incubated. Fifteen flasks then were treated for each test dose, positive control, and negative control. The flasks were incubated for a three-day period at 37°C in a humidified atmosphere containing 5% CO₂. The cells were then washed, and the incubation was continued for 4 weeks with refeeding twice a week. The assay was terminated by fixing the cell monolayers with methanol and staining Giemsa. The stained flasks were examined by eye and by microscope to determine the number of foci of transformed cells. The foci consisted of piled up and randomly oriented cells, sometimes with necrotic centers, on surrounding monolayers of normal cells.

Statistical tables provided by Kastenbaum and Bowman (1970) were used to determine statistical significance.

Precipitation conc: >250 ug/ml
Signed QA assurance statement provided.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint

21.06.2005

(6) (12)

Type : Mammalian cell gene mutation assay
System of testing : BALB 3T3 Mouse Cells
Test concentration : 0.00625 to 0.10000 ug/ml
Cycotoxic concentr. : 0.244 ug/ml
Metabolic activation : without

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Id 13752-51-7

Date 08.09.2005

Result : positive
Method :
Year : 1983
GLP :
Test substance : other TS: Commercial Cure-Rite® 18, purity: Not noted

Method : Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215

Remark : Clone 113 of BALB/3T3 mouse cells was obtained from Dr. Takeo Kakunga, NCI, Bethesda, MD. Subclones that were selected for low spontaneous frequencies of foci formation were used. Stocks were maintained in liquid nitrogen, and laboratory cultures were checked periodically for mycoplasma contamination. Cultures were grown and passed weekly in Eagle's Minimum Essential Medium (EMEM) supplemented with 10% fetal bovine serum.

The test chemical was dissolved in a small quantity of DMSO and then diluted with EMEM so the final concentration of DMSO was less than 0.5%. Lower concentrations were obtained by serial dilutions with EMEM. The dose range was based on the results of a clonal toxicity assay in which a series of 200 cells/dish were exposed in triplicate to a wide range of test chemical concentrations for 3 days. Five doses were selected to cover a wide range of toxicities from little or no reduction in colony-forming ability to a 50% reduction in the colony number. A negative control consisting of cells exposed to 0.5% DMSO in EMEM and a positive control treatment of 5µg/ml 3-methylcholanthrene (3-MCA) were also employed.

The transformation assay was based on the method of Kakunga (1973). Twenty four hours prior to treatment, a series of 25-cm² flasks was seeded with 104 cells/flask and incubated. Fifteen flasks then were treated for each test dose, positive control, and negative control. The flasks were incubated for a three-day period at 37°C in a humidified atmosphere containing 5% CO₂. The cells were then washed, and the incubation was continued for 4 weeks with refeeding twice a week. The assay was terminated by fixing the cell monolayers with methanol and staining Giemsa. The stained flasks were examined by eye and by microscope to determine the number of foci of transformed cells. The foci consisted of piled up and randomly oriented cells, sometimes with necrotic centers, on surrounding monolayers of normal cells.

Statistical tables provided by Kastenbaum and Bowman (1970) were used to determine statistical significance.

Precipitation conc: >250 µg/ml

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : Signed QA assurance statement provided.
 (2) valid with restrictions
 Meets generally accepted scientific standards, well documented and acceptable for assessment.

21.06.2005

(6) (12)

Type : Mouse lymphoma assay
System of testing : Mouse Lymphoma cell line L5178Y TK+/-
Test concentration : 0.313 to 35.0 µg/ml
Cycotoxic concentr. : With metabolic activation: Percent relative growth was 78.1% at 20.0 µg/ml and 5.7% at 35.0 µg/ml
 Without metabolic activation: Percent relative growth was 25.6% at 0.313 µg/ml and 3.8% at 1.880 µg/ml
Metabolic activation : with and without

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Result	:	positive
Method	:	
Year	:	1983
GLP	:	
Test substance	:	other TS: Commercial Cure-Rite® 18; purity = 95.6%.
Method	:	Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215
Remark	:	<p>Mouse Lymphoma cells (L5178Y TK+/-, clone 3.7.2C derived from the Fischer line from Dr. Donald Clive) were treated with doses of 0, 1.25, 5, 15, and 20 µg/ml. The negative solvent control was prepared by adding 0.1 DMSO per 10 ml of culture. The positive control was 0.5 µl/ml ethyl methanesulfonate under nonactivation conditions and) and 0.3 µl/ml dimethylnitrosamine under activation conditions. The assay procedure was very similar to the method of Clive and Spector (1975). Each treated culture consisted of 3x10⁶ cells suspended in 10 ml final volumes in 15 ml centrifuge tubes. Nonactivation and activation assays were conducted the same except the cell cultures in the activation assay contained the S-9, Aroclor 1254-induced liver preparation with cofactors. The cells were exposed to the test material dose for 4 hours, were washed, and were allowed an expression time of two days in growth medium. At the end of the expression period, 3x10⁶ cells from each treated culture were seeded in the selection medium (1x10⁶ cells per 100 mm dish). Cloning efficiency was determined by serially diluting a portion of the cells and seeding 300 cells in the nonselective cloning medium at 100 cells per 100 mm dish. BrdUrd-resistant colonies (TK-/- mutants) and viable colonies (nonselective medium) were counted after 10 days incubation at 37°C in a humidified atmosphere containing 5% CO₂. The ratio of resistant to viable colonies yielded the mutant frequency in units of 10⁻⁴. The average of the solvent and untreated negative control mutant frequencies was used as the background or spontaneous mutant frequency for each trial. A treated culture was considered to have a significantly elevated mutation frequency if the frequency exceeded 10x10⁻⁶ plus 1.5 times the background frequency. Additional criteria such as a dose or toxicity related response and repeatability between trial were also used to determine the presence of mutagenic activity.</p> <p>The test substance was positive with and without activation but only at doses that were very toxic.</p> <p>Precipitation conc: >250 µg/ml</p> <p>Signed QA assurance statement provided. Weakly active.</p>
Source	:	American Chemistry Council Rubber and Plastic Additives Panel
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards, well documented and acceptable for assessment.
21.06.2005		(6) (10)
Type	:	Mouse lymphoma assay
System of testing	:	Mouse Lymphoma cell line L5178Y TK+/-
Test concentration	:	0.313 to 50.0 µg/ml
Cycotoxic concentr.	:	With metabolic activation: Percent relative growth was 43.2% at 12.50 µg/ml and 4.2% at 50.0 µg/ml Without metabolic activation: Percent relative growth was 80.9% at 0.313 µg/ml and 7.9% at 1.880 µg/ml
Metabolic activation	:	with and without
Result	:	
Method	:	
Year	:	1983
GLP	:	

5. Toxicity

Id 13752-51-7

Date 08.09.2005

Test substance	: other TS: Commercial Cure-Rite® 18; purity: Not noted
Method	: Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215
Remark	: Mouse Lymphoma cells (L5178Y TK+/-, clone 3.7.2C derived from the Fischer line from Dr. Donald Clive) were treated with doses of 0, 1.25, 5, 15, and 20 µg/ml. The negative solvent control was prepared by adding 0.1 DMSO per 10 ml of culture. The positive control was 0.5 µl/ml ethyl methanesulfonate under nonactivation conditions and) and 0.3 µl/ml dimethylnitrosamine under activation conditions. The assay procedure was very similar to the method of Clive and Spector (1975). Each treated culture consisted of 3x10 ⁶ cells suspended in 10 ml final volumes in 15 ml centrifuge tubes. Nonactivation and activation assays were conducted the same except the cell cultures in the activation assay contained the S-9, Aroclor 1254-induced liver preparation with cofactors. The cells were exposed to the test material dose for 4 hours, were washed, and were allowed an expression time of two days in growth medium. At the end of the expression period, 3x10 ⁶ cells from each treated culture were seeded in the selection medium (1x10 ⁶ cells per 100 mm dish). Cloning efficiency was determined by serially diluting a portion of the cells and seeding 300 cells in the nonselective cloning medium at 100 cells per 100 mm dish. BrdUrd-resistant colonies (TK-/- mutants) and viable colonies (nonselective medium) were counted after 10 days incubation at 37°C in a humidified atmosphere containing 5% CO ₂ . The ratio of resistant to viable colonies yielded the mutant frequency in units of 10 ⁻⁴ . The average of the solvent and untreated negative control mutant frequencies was used as the background or spontaneous mutant frequency for each trial. A treated culture was considered to have a significantly elevated mutation frequency if the frequency exceeded 10x10 ⁻⁶ plus 1.5 times the background frequency. Additional criteria such as a dose or toxicity related response and repeatability between trial were also used to determine the presence of mutagenic activity. The test substance was positive with and without activation but only at doses that were very toxic. Precipitation conc: 1250 ug/ml Signed QA assurance statement provided.
Result	: With metabolic activation: weakly active Without metabolic activation: negative
Source	: American Chemistry Council Rubber and Plastic Additives Panel
Reliability	: (2) valid with restrictions Meets generally accepted scientific standards, well documented and acceptable for assessment.
Flag 21.06.2005	: Critical study for SIDS endpoint (6) (10)

5.6 GENETIC TOXICITY 'IN VIVO'

Type	: Dominant lethal assay
Species	: rat
Sex	: male/female
Strain	: Sprague-Dawley
Route of admin.	: gavage
Exposure period	: 56 consecutive days to males
Doses	: 0, 6.25, 12.5, or 25 mg/kg. (0.25 mg/kg triethylenemelamine positive control)
Result	: negative
Method	:

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Year	:	1982
GLP	:	yes
Test substance	:	other TS: Commercial Cure-Rite® 18; Purity = 95.6%
Method	:	Hinderer, R.K., M. Knickerbocker, and F.J. Koschier (1982). Toxicol. Appl. Pharmacol. 62:335-341.
Result	:	<p>The test material (0, 6.25, 12.5, or 25 mg/kg) in corn oil was administered by gavage for 56 consecutive days to groups of male Sprague-Dawley rats (10 animals per group). The negative vehicle control group received corn oil while the positive control received a single ip dose of 0.25 mg/kg triethylenemelamine 1 day prior to mating. On the day following the last treatment, each male was cohabited with two sexually mature female rats for 1 week. The females were then removed and replaced with two more females for 1 week. Females were checked for vaginal plugs indicating that matings had occurred. Thirteen days after the midpoint of each cohabitation, all females were sacrificed and subjected to uterine examination. For each female numbers of corpora lutea, implantation sites, live fetuses, and early and late absorptions were recorded. After completion of the mating period, 3 males per treatment group were randomly selected for necropsy. The liver spleen, kidneys, heart, brain, adrenals, and thyroid were weighed and organ-to-body weight ratios were calculated. Data were analyzed for statistical significance.</p> <p>A significant depression in body weight gain was observed in the males administered the highest dose. Similar pregnancy rates were observed in all test groups compared with the controls. No evidence of dominant lethal mutations were observed in the test groups. In the TEM positive controls, the number of implantation sites and preimplantation losses were significantly decreased, and the number of early fetal deaths per pregnant female were significantly elevated.</p>
Source	:	American Chemistry Council Rubber and Plastic Additives Panel
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards, well documented and acceptable for assessment.
Flag	:	Critical study for SIDS endpoint
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5.7 CARCINOGENICITY

Species	:	rat
Sex	:	male/female
Strain	:	Sprague-Dawley
Route of admin.	:	oral feed
Exposure period	:	2 years
Frequency of treatm.	:	continuous daily
Post exposure period	:	none
Doses	:	0, 20, 60, 200, or 600 ppm
Result	:	
Control group	:	yes, concurrent no treatment
Method	:	
Year	:	1986
GLP	:	
Test substance	:	other TS: Commercial Cure-Rite® 18; purity = 96.8%
Method	:	Hinderer, R.K., G.R. Lankas, A.L. Knezevich, and C.S. Auletta (1986). Toxicol. Appl. Pharmacol. 82:521-531
Result	:	<p>Diets containing 0, 20, 60, or 600 ppm of the test material were administered to groups (60/sex/group) of Sprague-Dawley rats for 112 weeks. Ten rats/sex/group were identified for a 12 month interim sacrifice. Animals were checked twice daily for mortality and gross signs of toxicity. A</p>

detailed physical exam palpation for tissue masses was performed weekly. Body weight and feed consumption were measured weekly through week 12 and biweekly from week 13 to 26 and monthly thereafter. Hematology, clinical chemistry, and urinalysis were conducted pretest on 15 animals/sex and at months 6, 12, 18, and 24. Animals were given a complete gross post mortem examination following spontaneous death, death in extremis, or scheduled sacrifices. A full set of organs were subjected to gross and histological examination. All tissues from the control and high dose were processed for pathological examination at 12 months and termination. Tissues in mid and low dose groups were identified for pathological evaluation based on the pathological evaluations in the controls and high dose groups. Organs also were weighed. Furthermore, the testes from 3 of the 10 males at 12 months were processed for electron and light microscopy examination. Statistical analyses were conducted on the end points.

A compound related increase in tumors of the urinary system was observed in the high dose group: males (kidney: urothelia carcinoma, 2/60; squamous cell carcinoma, 1/60; ureters: urothelial carcinoma 4/6 [2 in one male]; urinary bladder: urothelial papilloma, 3/59; urothelial carcinoma, 4/59; squamous cell papilloma, 1/59; squamous cell carcinoma, 2/59; combined total neoplasms: 17 vs 1 urothelial papilloma in the control); females (kidney: urothelial papilloma, 1/60; urothelia carcinoma, 3/60; squamous cell carcinoma, 3/60; ureters: urothelial carcinoma 2/8; urinary bladder: urothelial papilloma, 3/59; urothelial carcinoma, 2/59; squamous cell papilloma, 2/59; squamous cell carcinoma, 1/59; combined total neoplasms: 15 vs 0 in the control). Tumors of the urinary system were not found in the mid and low dose groups. Ureters were not evaluated in the controls, low or mid dose groups.

Kidney weights, non-neoplastic urinary tract abnormalities, and rales was observed in the high dose males and females. Body weights also were significantly lower in the high dose males and females. No compound-related effects on hematology, clinical chemistry, or urinalysis were noted.

Source : American Chemistry Council Rubber and Plastic Additives Panel
Reliability : (1) valid without restriction
 Meets generally accepted scientific standards, well documented and acceptable for assessment.

Flag : Critical study for SIDS endpoint

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(8)

5.8.1 TOXICITY TO FERTILITY

Type : Fertility
Species : rat
Sex : male/female
Strain : Sprague-Dawley
Route of admin. : oral feed
Exposure period : 12 weeks
Frequency of treatm. : daily
Premating exposure period
 Male : Males were sacrificed over a 6-7 day period following the 21-day mating period.
 Female :
Duration of test : 12 weeks
No. of generation studies :
Doses : 0, 60, 200, or 600 ppm.
Control group : yes, concurrent no treatment
NOAEL parental : 200 ppm

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NOAEL F1 offspring	:	600 - ppm
Method	:	
Year	:	1987
GLP	:	yes
Test substance	:	other TS: Commercial Cure-Rite® 18; purity = 98.0%.
Method	:	Hinderer, R.K., B.Y. Cockrell, S.M. Debanne, and P.T. Goad. (1987). Fund. Appl. Toxicol. 9:763-772.
Remark	:	The test material (0, 60, 200, or 600 ppm) was administered in the diet to groups of male Sprague-Dawley rats (12 animals per group) for up to 12 weeks. Following 56-days of treatment each male was cohabited nightly with two females until a sign of mating (sperm in a vaginal smear) was observed or for 21-days. During the 21-day period, feeders were removed from the male's cage for nightly cohousing. A similar regimen was used for the control males; control males received the basal diet only. Females received the untreated diet throughout the study. Females were examined each morning for evidence of mating. Estrous cycle data were recorded during the mating period for each female until evidence of gestation was observed (Day 0 of gestation). Following mating the female was removed from the mating unit and housed individually for the remainder of gestation and lactation.
Result	:	<p>NOAEL : 600 ppm</p> <p>No clear dose-related effect on body weights was observed in either the parents or the pups. However, body weight gain was significantly higher in the low dose parental males. No evidence of compound related effects on mating, fertility, gestation length, number of implantations or live birth, pup growth, or survival was observed.</p> <p>No morphological changes in the testes from the high dose males was observed by either light or electron microscopy.</p> <p>Toxicity to offspring: None</p> <p>Also, no pathological findings in female reproductive tissues</p>
Source	:	American Chemistry Council Rubber and Plastic Additives Panel
Reliability	:	(2) valid with restrictions
Flag	:	Critical study for SIDS endpoint
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5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

Type	:	other: Oral reproduction/developmental toxicity screening study
In vitro/in vivo	:	In vivo
Species	:	rat
Sex	:	male/female
Strain	:	Sprague-Dawley
Route of admin.	:	oral feed
Exposure period	:	Males: 14 day premating and 14 day mating period Females: 14 day premating period through mating, gestation and lactation day 4
Frequency of treatm.	:	continuously in the diet
Duration of test	:	
Doses	:	60, 200, 600 ppm
Control group	:	yes, concurrent vehicle

Result	: NOAEL for adults was 600 ppm NOEL for offspring was 600 ppm
Method	: other: OECD 421
Year	: 2005
GLP	: yes
Test substance	: other TS: Cure-Rite®, purity: 98.5%
Method	<p>: The test material was administered in the diet to groups of ten male and ten female rats throughout maturation, mating, gestation and up to Day 4 post partum. The dose levels were 60, 200 and 600 parts per million (ppm) with a same sized group receiving vehicle (PMI powdered diet) alone. Following fourteen days of dosing, male and female rats were paired within their dose groups to produce litters. On Day 5 post partum, all surviving animals were killed and examined macroscopically.</p> <p>Parental animals were observed weekly for clinical signs. Bodyweights and food consumption were recorded weekly during the maturation phase which was continued for males after the mating phase. Mated females were weighed on Days 0, 7, 14 and 20 post coitum and Days 1 and 4 post partum and food consumptions recorded between Days 1 to 7, 7 to 14 and 14 to 20 post coitum and 1 to 4 post partum.</p> <p>The offspring were observed daily for clinical signs. The litter signs and individual pup bodyweights were recorded on Days 1 and 4 post partum. During the lactation period the offspring were observed for intra-litter onset and duration of landmarks of physical development. On specific days of lactation, reflexological assessment of offspring was performed.</p> <p>Post mortem macroscopic examinations were performed on all adults and offspring including decedents. Reproductive and potential target organs and any significant abnormalities from all parental animals were preserved in fixative. Histopathology was carried out on reproductive and target organs from control and high dose group parental animals.</p> <p>Statistical methods</p> <p>The following parameters were analysed statistically, where appropriate using the test methods outlined as follows:</p> <p>Adult male and female bodyweight during the maturation, gestation and lactation periods, adult male food consumption, female food consumption during maturation, gestation and lactation, litter size, litter weight, individual offspring bodyweight, offspring landmarks of physical development, reproductive and viability indices and adult organ weights.</p> <p>Values were analysed to establish homogeneity of group variances using Bartlett's chi-square test followed by one-way analysis of variance. If the variances were unequal subsequent comparisons between control and treated groups were performed using student's t-test assuming unequal variances. If variances were equal subsequent comparisons between control and treated groups were performed using Dunnett's Multiple Comparison Method.</p> <p>Adult pre-coital intervals, female gestation lengths, offspring reflexological responses and litter sex ratios, relative organ weights. Individual values were compared using Kruskal-Wallis non-parametric rank sum test. Where significant differences were seen, pairwise comparison of control values against treated group values was performed using Mann-Whitney "U" test.</p> <p>Histopathological findings were evaluated using Chi-squared analysis for differences in the incidence of lesions occurring with an overall frequency of 1 or greater.</p> <p>Kruskal-Wallis one-way non-parametric analysis of variance for the comparison of severity grades for the more frequently observed conditions.</p>
Result	: Adults At 600 ppm there were no adult mortalities or clinical signs of toxicity. An initial reduction in food consumption lead to a transient reduction in bodyweight gain. No macroscopic or microscopic abnormalities were

observed at post mortem examination.
At 200 ppm there were no signs of test material toxicity.
At 60 ppm there were no signs of test material toxicity.
There were no treatment-related effects on fertility, mating performance, gestation length and subsequent offspring pre or post -natal viability growth or development.

Offspring

There were no treatment-related effects upon litter size at birth or on subsequent offspring survival throughout lactation. At 600 ppm there was a statistically significant reduction in group mean offspring weight on Day 1 and Day 4 post partum. However, as litter sizes and group mean total litter weight was comparable between all dose groups, at this dose level, this was considered to be incidental and not related to treatment. There were no effects on offspring reflexological responses and no effect on the intra-litter sex ratios.

Reliability : (1) valid without restriction
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5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

- (1) BFGoodrich MSDS
- (2) Bio/dynamics Inc., East Millstone, NJ (1980) Project #6216-80
- (3) Bio/dynamics Inc., East Millstone, NJ (1980) Project # 6217-80
- (4) Biosearch Inc, Philadelphia, PA(1981)
- (5) Hill Top Research, Inc., Miamiville, Ohio (1971)
- (6) Hinderer, R.K., B. Myhr, D.R. Jagannath, S.M. Galloway, S.W. Mann, J.C.Riddle, and D.J. Brusick (1983) Environ. Mutagen. 5:193-215
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10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT